DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

November 5, 2014

Nibec Company Limited
C/O Mr. Daniel Nam
PATs Corporation
General Manager
4568 W. 1St Street, Suite 104
Los Angeles, CA 90004

Re: K133507
Trade/Device Name: GuidOss®
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: II
Product Code: NPL
Dated: September 2, 2014
Received: September 8, 2014

Dear Mr. Nam:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

INDICATION FOR USE

510(k) Number: K133507

Device Name: GuidOss®

INDICATIONS FOR USE:

GuidOss® is recommended for:

1. Simultaneous use of membrane (GuidOss®) and implants :
2. Augmentation around implants placed in placed in immediate extract sockets;
3. Augmentation around implants placed in delayed extraction sockets;
4. Localized ridge augmentation for later implantation;
5. Alveolar ridge reconstruction for prosthetic treatment
6. Filling of bone defects after root resection, cystectomy, removal of retained teeth.
7. Guided bone regeneration in dehiscence defects; and
8. Guided tissue regeneration procedures in periodontal defects.

Prescription Use √ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____ (21 CFR 801 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary

Sponsor/Applicant

NIBEC Co., Ltd.
Iwol electricity-electronic Agro-industrial Complex,
1127, Sinwol-ri, Iwol-myeon, Jincheon-gun, Chungcheongbuk-do, Korea
Phone: 82-10-2889-8590
Fax: 82-2-744-8732
Contact: Dr. Park, Yoon-Jeong

Date Prepared : October 24, 2013

Device Name and Identification

Proprietary Name:	GuidOss®
Common/Usual Name:	Resorbable Collagen Membrane
Classification Name:	Barrier, Animal Source, Intraoral

Predicate devices

Bio-Gide® Resorbable Bilayer Membrane for Guided Tissue and Bone Regeneration (K050446)
Manufactured by:
Geistlich Pharma AG
Bahnhofstrasse 40
CH-6110 Wolhusen
Switzerland

CollaDental Barrier, Collagen dental matrix, Dressing, Wound (K100695)
Manufactured by:
Collamatrix Inc.
1F, No. 50-1, Keyan Road, Jhunan Science Park
Miaoli County, 350, Taiwan

Device Category/Class

Device Class:	Class II
Regulation Number:	21 C.F.R. 872.3930
Product Code:	NPL

Indication for use

GuidOss® is recommended for:

1. Simultaneous use of membrane (GuidOss®) and implants :
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3. Augmentation around implants placed in delayed extraction sockets;
4. Localized ridge augmentation for later implantation;
5. Alveolar ridge reconstruction for prosthetic treatment
6. Filling of bone defects after root resection, cystectomy, removal of retained teeth.

7. Guided bone regeneration in dehiscence defects; and
8. Guided tissue regeneration procedures in periodontal defects.

Device Description

GuidOss® is made from pure type I collagen membrane obtained by a standardized controlled manufacturing process. The type I collagen is obtained from veterinary certified porcine and is carefully purified to avoid immunological reactions. GuidOss® membrane is manufactured by fibrillogenesis and crosslinking. The collagen fibers are self-assembled by the process of fibrillogenesis. The crosslinked collagen fibers exhibited increased mechanical strength, thermal stability and increased resistance to pepsin digestion compared to non-crosslinked collagen.

Basis for Substantial Equivalence

GuidOss® resorbable collagen membrane Consists of Material (porcine Collagen) that is very similar in material composition to the predicate devices, Bio-Gide® (porcine Type 1, 3 Collagen), CollaDental Barrier® (porcine Type 1 Collagen). Design, function and intended use are substantially equivalent to the corresponding characteristics of the predicate devices. Although minor differences exist in terms of manufacturing processing, medical device packaging, and handling characteristics GuidOss® resorbable collagen membrane and the two predicate devices, these minor differences raise no new issues of safety and efficacy of GuidOss® resorbable collagen membrane.

The following is a table comparing GuidOss®, Bio-Gide® and CollaDental Barrier® a collagen membrane cleared for GTR and GBR.

Table 1: Substantial Equivalence Comparison

Property	GuidOss®	Bio-Gide® (K050446)	CollaDental Barrier® (K100695)
Similar **Intended Use**	Used for guided tissue regeneration procedures in periodontal defects to enhance regeneration of the periodontal apparatus.	Used for guided tissue regeneration procedures in periodontal defects to enhance regeneration of the periodontal apparatus.	Used for guided tissue regeneration procedures in periodontal defects to enhance regeneration of the periodontal apparatus.
Target population	Human oral, periodontal	Human oral, periodontal	Human oral, periodontal
Dosage form	Collagen membrane contained in double blisters	Collagen membrane contained in double blisters	Collagen membrane contained in double blisters
Material	Type I collagen	Type I and Type III collagen	Type I collagen
Animal source	porcine	porcine	porcine
Physical Morphology	Collagen fibers	Collagen fibers	Collagen fibers
Biocompatible	Biocompatible, as	Biocompatible (as demonstrated in	Biocompatible (as demonstrated in

	demonstrated by : - Genotoxicity testing - Micronucleus Test for Genetic Toxicology - Intracutaneous reactivity testing - Maximization and sensitization testing - Pyrogen testing - Acute systemic injection testing - Cytotoxicity testing - Implantation testing - Preclinical safety and efficacy testing - Clinical case series	published literature)	published literature)
Performance	Periodontal Regeneration	Periodontal Regeneration	Periodontal Regeneration
Compatibility w/other devices	Can be used with Bone grafting material	Can be used with Bone grafting material	Can be used with Bone grafting material
Sterilization Process	Sterile by Gamma Irradiation	Sterile by Gamma Irradiation	Sterile by Gamma Irradiation
Chemical safety	Biocompatible	Biocompatible	Biocompatible
Anatomical sites	Oral, Periodontal	Oral, Periodontal	Oral, Periodontal
Non-Pyrogenic	Yes	Yes	Yes
Shelf-Life	36 Months	36 Months	36 Months

Brief Summary of Data Submitted

The Sponsor evaluated the performance characteristics of GuidOss® and Bio-Gide® with a thorough chemical and physical characterization. The physical and chemical characteristics of the products were found to be comparable. Further, in several animal studies, both products were found to grow new bone and be subsequently resorbed at similar rates. Finally, in a clinical case series, use of GuidOss® resulted in defect healing and formation of new bone of sufficient quality to obtain dental implant placement.

GuidOss® was the subject of the full range of biocompatibility tests recommended in the FDA's "Class II Special Controls Guidance Document: Dental Bone Grafting Devices" and in accordance with ISO 10993. Test results confirmed product safety. GuidOss® is made from pure type I collagen membrane obtained by a standardized controlled manufacturing process. The type I collagen has been purified from veterinary certified porcine skin. Further, the product is sterilized to achieve a sterility assurance level SAL 1 x $10^{-6.}$

Based on the information presented herein, it has been demonstrated that GuidOss® is substantially equivalent to Bio-Gide®, and safe and effective for the proposed indications for use.

Conclusion

The GuidOss® presents the same types of potential risks to consumers as the predicate device Bio-Gide®, and has controlled these risks in a similar manner. Accordingly, GuidOss® is expected to be safe and effective for its intended uses. And biocompatibility tests and compatibility test show that the device meets the requirements of those standards.

Literatures and post market experience show that the device is substantially equivalent. Comparison with the predicate device shows that the device has similar specification and performance. Therefore, it is concluded that GuidOss® are substantially equivalent to the predicate device.